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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,989	12/14/2001	Peter David Davis	U 013589-7	1811

140 7590 09/23/2003

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EXAMINER

YU, MISOOK

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 09/23/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/890,989

Applicant(s)

DAVIS, PETER DAVID

Examiner

MISOOK YU, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2003 and 14 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-10,13,14,17,19-21,24 and 25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-10,13,14,17,19-21,24 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5-29-2003 has been entered.

Claims 1, 2, 4-10, 13, 14, 17, 19- 21, 24, and 25 are pending and examined on merits.

Claim Rejections - 35 USC § 112

The rejection of claims under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is **withdrawn** either in view of amendment and/or persuasive argument.

Claims 4-8, and 17, 19-21 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4 and 8 recite "ortnithine" but it is not clear what the metes and bounds are. It appears to be spelling error.

Claim 10 recites the limitation "the nitric oxide inhibitor" in line 1. There is insufficient antecedent basis for this limitation in the claim. The instant claim depends on claim 1, which does not recite "nitric oxide inhibitor".

Claim 14 recites the limitation "the tubulin binding agent and nitric oxide inhibitor" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claims 17, 19, and 20 recite "excipient" but it is not clear what the metes and bounds are. It appears to be spelling error.

Claims 17, 19, and 10 recite the limitation "the method of administration" in line 2. There is insufficient antecedent basis for this limitation in the claim. The instant claims depend on the base claim, which does not recite any method of administration.

The rejection of claims under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is **withdrawn** in view of the amendment.

The rejection of claims under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is **withdrawn** because applicant argument is persuasive.

Priority

Priority to the PCT and GB application is granted because applicant's argument is persuasive.

Claim Rejections - 35 USC § 102

The rejection of claims under 35 U.S.C. 102(b) as being anticipated by Tozer et al (April 1, 1999, Cancer Res. Vol. 59, pages 1626-1634) is **withdrawn** because Tozer et al is no longer art in view of granting the priority above.

Claim 1 is newly rejected under 35 U.S.C. 102(b) as being anticipated by Bonfoco et al (1995, Experimental Cell Research, vol. 218, pages 189-200).

The claim is interpreted as drawn to composition comprising a tubulin binding agent and an NO synthase inhibitor. The claim read on the composition *per se* and the intended use in the preamble is not given patentable weight for purposes of comparing the claim with the prior art. Bonfoco et al teach composition comprising a tubulin binding agent and an NO synthase inhibitor. Note Table I and 2 at page 198.

Claim Rejections - 35 USC § 103

The rejection of claims under 35 U.S.C. 103(a) as being unpatentable over Narayanan et al (J. Biol. Chem. 1995, 270, 11103-10, see abstract only) and Stenger (Eur. J. Pharmacol. 1995, 294, 703-12, see abstract only) and WO-A-9509621 (provided in ISR, 4-13-1995) as applied to claims 1-5, 9-15, 16-20 above, and further in view of Tozer et al (April 1, 1999, Cancer Res. Vol. 59, pages 1626-1634) is **withdrawn** because the primary reference is no longer art.

Claims 2, 4-10, 13, 14, 17, 19- 21, 24, and 25 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Chaplin et al (1998, a copy provided with ISR, Seminars in Radiation Oncology, vol. 8, pages 151-163).

The claims are interpreted as drawn to composition comprising two genres, i.e. a tubulin binding agents and an NO synthase inhibitor with the specific agents belong to the two genres recited in the dependent claims, and method of using said composition for inhibiting unwanted angiogenesis. Chaplin et al teaches the various recited agents belonging to the two genres are known in the art and had been used in inhibiting unwanted angiogenesis. The instant claims can be viewed as a composition and methods drawn to administering a combination of ingredients known in the art to be useful for the same purpose, i.e. an *In re Kerkhoven* analysis (*In re Kerkhoven*, 626, F.2s 846, 850, 205 USPQ 1069, 1072 (CCPA 1980)). The court held that it is obvious to combine two compositions, in order to form a third composition, when each of the two compositions is taught by the prior art to be useful for the same purpose. The idea of combining them flows logically from their having been individually taught in the prior art (MPEP 2144.06). Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine a tubulin binding agent and a NO synthase inhibitor known to be useful for the treatment of inhibiting angiogenesis because the prior art teaches that both are useful for inhibiting angiogenesis.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Misook Yu

September 21, 2003


ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
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